UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,112	01/25/2002	Kurt Osther	45579/56876	1887

7590 11/01/2004

STEPHANA E. PATTON
EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,112	OSTHER ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2004 and 19 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-33,39-42 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-33,39-42 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 11, 2004 have been fully considered but they are not persuasive. The applicant's arguments were found non-persuasive by the examiner. With reference to the applicant's argument that the specification enables the membrane to be "cell-free" was not found persuasive by the examiner. The membrane used by the applicant is made of tissue, collagen type I, as claimed in claim 33, which tissue, as known in the art may contain cells. Nowhere in the specification does the applicant disclose removal of cells from the membrane, and nowhere in the specification does the applicant disclose the membrane to have an absence or omission of cells. Therefore, the specification does not preclude the use of cells in the membrane. See MPEP 706.03(o). Referring to the applicant's arguments that Vibe-Hansen (US 5,759,190), Athanasiou et al. (US 5,876,452), Pachence et al. (US 6,080,194), and Schwartz et al. (US 6,251,143) do not disclose the claimed invention, is found non-persuasive by the examiner. With reference to the Vibe-Hansen rejection, the examiner's position is believed to be adequately described in the response to arguments and rejection portions of the final office action mailed April 14, 2004. With reference to applicant's arguments that the Schwartz and Athanasiou references do not contain a composition on the surface of the membrane, but rather within, this is found non-persuasive by the examiner. Even if the compositions were within the membranes of Schwartz and Athanasiou, the compositions would be uniform throughout and extend to the surface, therefore, the surface would carry the composition also. With reference to applicant's argument that the Pachence reference does not disclose a stimulation molecule is found non-persuasive by the examiner. Pachence's membrane is made of collagen I, and

therefore, collagen I proteins (of which collagen proteins are claimed by applicant to be stimulation molecules) would exist in the collagen I membrane.

Response to Amendment

The declaration under 37 CFR 1.132 filed October 19, 2004 is insufficient to overcome the rejection of claims 29-33, 39-42, and 52 based upon Schwartz et al. Vibe-Hansen et al., Pachence et al., and Athanasiou et al. as set forth in the last Office action because: see comments above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-33, 39-42, and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 29-33, 39-42, and 52 recite, "A cell-free cartilage membrane". The cartilage membrane was not found in the specification to be referred to as "cell-free", and does not disclose anywhere the absence of cells, benefit of having an absence of cells, or even the removal of cells (seeing as the membrane is made of collagen I, a natural tissue where cells may be present). In fact, the applicants entire invention seems to focus on the idea of cells growing or invading the membrane, and even discloses cells inside the membrane (pg.14, lines 32-35) and in

all drawings, the membrane is in contact with the suspension of cells at the membranes surface. Therefore, "A cell-free cartilage membrane" is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-33 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Vibe-Hansen et al. (USPN 5,759,190, cited by applicant in IDS). Referring to claims 29 and 52, Vibe-Hansen discloses a cell free cartilage membrane and kit (col.2, lines 35-40) comprising at least one surface part carrying a composition comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins (collagens I, II, III.; col.7, lines 1-5, 10-12; col.8, lines 43-45) and non-collageneous proteins (fibronectin and fibrinogen, col.5 lines 7-10, are both in or attached to the patch, even though they are elements of the Tisseel adhesive, and applicant has argued that they will not create a signal transduction, this in non-persuasive, because applicant has listed specifically fibronectin and fibrinogen in claim 30 to be elements which are non-collageneous proteins that induce a signal transduction, and Vibe-Hansen has disclosed the exact elements and therefore, Vibe-Hansen has disclosed what the applicant has claimed).

Referring to claim 30, Vibe-Hansen discloses a collagen protein being collagen II (col.8, lines 43-45, 50-51), and a non-collageneous protein being fibronectin (col.5, lines 7-10, see above).

Referring to claims 31-32, Vibe-Hansen discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.2, lines 28-35).

Referring to claim 33, Vibe-Hansen discloses the membrane being a natural or synthetic collagen type I membrane (col.7, lines 9-13).

Claims 29, 31, 32, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Athanasiou et al. (USPN 5,876,452, cited by applicant in IDS). Referring to claims 29 and 52, Athanasiou discloses a cell free (Athanasiou discloses cells *may* be included, although not necessary, therefore, Athanasiou's implant may be cell free, col.10, lines 13-15) cartilage membrane (implant) and kit comprising at least one surface part carrying a composition (bioactive agent) comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins (col.9, lines 28-49).

Referring to claims 31-32, Athanasiou discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.9, lines 19-21).

Claims 29, 31-33, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Pachence et al. (USPN 6,080,194, cited in previous office action). Referring to claims 29 and 52, Pachence discloses a cell free cartilage membrane (12) and kit (col.1, lines 6-10; col.4, lines

28-32; Example 3; may be with or *without* cells) comprising at least one surface part carrying a composition comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins.

Referring to claims 31-32, Pachence discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.3, lines 33-35).

Referring to claim 33, Pachence discloses the membrane being a natural or synthetic collagen type I membrane (col.5, lines 1-2).

Claims 29-33, 39-42, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al. (USPN 6,251,143 B1, cited in previous office action). Referring to claims 29 and 52, Schwartz discloses a cell free (may or may not include cells, Schwartz discloses a membrane having an attachment factor and/or cell, col.4, lines 16-30; col.11, lines 9-12, therefore the cells need not be included and may be cell free) cartilage membrane (16) and kit comprising at least one surface part carrying a composition comprising at least one stimulation molecule (attachment factor), which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins (col.4, lines 16-26; col.11, lines 8-20).

Referring to claim 30, Schwartz discloses a collagen protein being collagen II, VI, IX, XI, a proteoglycan being aggrecans, decorin, fibromodulin, biglycan, and a non-collageneous protein being cryoprecipitate, fibronectin, vitronectin, fibrinogen, fibrillin, kistrin, echistatin, von Willebrand factor, tenascin, or anchorin CII (col.4, lines 16-26; col.11, lines 8-20).

Referring to claims 31-32, Schwartz discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (16; col.7, lines 46-48).

Referring to claim 33, Schwartz discloses the membrane (16) being a natural or synthetic collagen type I membrane (col.10, lines 58-66).

Referring to claims 39-42, Schwartz discloses the stimulation molecule comprising at least one RGD motif, a natural or synthetic protein or peptide or fusion, collagen II or fibronectin (col.4, lines 16-26; col.11, lines 8-20), and wherein the stimulation molecule (attachment factor) is attached to a support (16).

Claims 29-32, 39-42, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubo et al. (US 5,236,447). Referring to claims 29 and 52, Kubo discloses a membrane (10) and kit (fig.1, 10) comprising a membrane (10; that could be used for cartilage, this is intended use language, and Kubo's membrane is capable of functional at that location) comprising at least one surface part carrying a composition selected from the group consisting of collagen proteins, non-collagen proteins, or proteoglycans (composition, col.3, lines 59-65; col.7, lines 51-55).

Referring to claims 30 and 39-41, Kubo discloses a stimulation molecule comprising collagen (therefore, collagen proteins, natural proteins), fibrinogen, and fibronectin (which has an RGD motif), see col.3, lines 59-65).

Referring to claims 31-32, Kubo discloses a non-immunogenic, non-toxic, biodegradable membrane (col.3, lines 15-17, 50-59), which is substantially porous (the membrane is a woven fabric, so inherently has pores, and more are created as they absorb, col.3, lines 66-69).

Referring to claim 42, Kubo discloses a stimulation molecule (coating, protein, col.3, lines 59-65) attached to a support (membrane 10).

Claims 29-33, 39-42, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (US 5,206,028). Referring to claims 29 and 52, Li discloses a membrane and kit (which may be used for any medical application, col.5, lines 28-42) comprising a membrane (membrane matrix, col.1, lines 7-9; col.3, lines 60-61) comprising at least one surface part carrying a composition (additive, col.6, lines 59-68) selected from the group consisting of collagen proteins, non-collagen proteins, or proteoglycans.

Referring to claims 30 and 39-41, Li discloses a stimulation molecule comprising proteins, proteoglycans, and fibronectin (which has an RGD motif), see col.6, lines 59-69.

Referring to claims 31-33, Li discloses a non-immunogenic, non-toxic, biodegradable membrane (collagen is inherently degradable, col.10, lines 58-60) which is substantially porous (col.4, lines 16-21), and comprising collagen type I (col.4, lines 56-59; col.5, lines 59-60).

Referring to claim 42, Li discloses a stimulation molecule (additive, col.6, lines 59-69) attached to a support (membrane matrix).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700